



Pancreatic Islets and Parathyroid Gland Co-transplantation for Treatment of Diabetes in the Intra-Muscular Site: PARADIGM

Grant Award Details

Pancreatic Islets and Parathyroid Gland Co-transplantation for Treatment of Diabetes in the Intra-Muscular Site: PARADIGM

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-11437

Investigator:

Name: Peter Stock

Institution: University of California, San

Francisco

Type: PI

Disease Focus: Diabetes, Metabolic Disorders, Type 1 diabetes

Human Stem Cell Use: Adult Stem Cell

Award Value: \$11,083,012

Status: Pre-Active

Grant Application Details

Application Title: Pancreatic Islets and Parathyroid Gland Co-transplantation for Treatment of Diabetes in the Intra-

Muscular Site: PARADIGM

Public Abstract:

Therapeutic Candidate or Device

Human pancreatic islets and parathyroid gland combination graft

Indication

Patients with established Type 1 diabetes

Therapeutic Mechanism

Pancreatic islet transplantation has become a more viable approach to treat patients with established Type 1 diabetes. However, widespread application has been limited by several barriers, most importantly, poor islet survival and an inability to monitor islets after transplant. Cotransplantation of parathyroid tissue with pancreatic islets leads to dramatic improvement in islet survival and function after intramuscular transplant, which enables easy access and monitoring.

Unmet Medical Need

The ability to restore long-term normal blood glucose levels with islets from a single donor, using a low morbidity procedure, in a retrievable site that can be non-invasively monitored has not been attainable previously. The PARADIGM trial is aimed at addressing this critical unmet need.

Project Objective

Phase I/IIa trial completed

Major Proposed Activities

- Perform phase I/IIa safety and efficacy trial of pancreatic islet and parathyroid cotransplantation in the muscle of patients with Type 1 diabetes
- Perform safety analysis and efficacy assessment of islet and parathyroid grafts in a novel intramuscular islet transplant site
- Perform exploratory studies on islet engraftment mechanisms and immunologic monitoring of pancreatic islet and parathyroid grafts

Statement of Benefit to California:

Diabetes affects 2.3 million Californians with annual healthcare costs of over \$12 billion. If successful, this work can lead to a more effective therapy that directly benefits patients with Type 1 diabetes and those who are on insulin therapy. By developing a retrievable transplant site, it also paves the way for future clinical translation of stem cell-derived islets that can potentially invigorate research and biotechnology development in California.

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